



## DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 2

[Docket No. APHIS-2020-0101]

RIN 0579-AC69

Handling of Animals; Contingency Plans

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Animal and Plant Health Inspection Service issued a final rule on December 31, 2012, to establish regulations under which research facilities and dealers, exhibitors, intermediate handlers, and carriers must meet certain requirements for contingency planning and training of personnel. Implementation of the final rule was stayed on July 31, 2013, so that the agency could conduct additional review to further consider the impact of contingency plan requirements on regulated entities. Since that time, we have conducted such a review, and the 2021 Congressional Appropriations Act has required us to propose to lift the stay. We are therefore lifting the stay and making minor revisions to the requirements in order to update compliance dates and clarify intent. The lifting of the stay and proposed revisions will better ensure that entities responsible for animals regulated under the Animal Welfare Act are prepared to safeguard the health and welfare of such animals in the event of possible emergencies or disasters.

DATES: Effective [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Elizabeth Theodorson, DVM, MPH,  
Assistant Deputy Administrator, Animal Care, APHIS, 4700 River Road Unit 86, Riverdale, MD  
20737; (970) 494-7473.

SUPPLEMENTARY INFORMATION:

## Background

Under the Animal Welfare Act (AWA) (7 U.S.C. 2131 *et seq.*), the Secretary of Agriculture is authorized to promulgate standards and other requirements governing the humane handling, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, carriers, and intermediate handlers. The Secretary has delegated authority for administering the AWA to the Administrator of the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS). Within APHIS, the responsibility for administering the AWA has been delegated to the Deputy Administrator for APHIS' Animal Care program (AC). Regulations and standards established under the AWA are contained in 9 CFR parts 1, 2, and 3 (referred to below as the regulations).

Following the events experienced during the 2005 hurricane season, AC concluded that entities responsible for animals covered by the AWA could better safeguard the health and welfare of their animals by developing contingency plans for possible emergencies or disasters. Consequently, on December 31, 2012, APHIS published in the *Federal Register* (77 FR 76815-76824, Docket No. APHIS-2006-0159) a final rule<sup>1</sup> establishing regulations under which research facilities and dealers, exhibitors, intermediate handlers, and carriers of animals regulated under the AWA must meet certain requirements for developing contingency plans and training personnel in their role and responsibilities related to the contingency plan.

After learning that a number of small entities considered the requirements of these regulations excessive for their specific cases, and determining there to be validity to such a claim, on July 31, 2013, we published in the *Federal Register* (78 FR 46255, Docket No. APHIS-2006-0159) a stay<sup>2</sup> of the regulations to reexamine any unique circumstances and costs that may vary by the type and size of businesses affected by the final rule.

---

<sup>1</sup> To view the final rule, go to <https://www.regulations.gov/document/APHIS-2006-0159-0209>.

<sup>2</sup> To view the stay of the regulations, go to <https://www.regulations.gov/document/APHIS-2006-0159-0214>.

Since that time, APHIS has issued *de minimis* exemptions to animal licensure that we believe address the concerns that led to the stay. Additionally, on December 27, 2020, the 2021 Congressional Appropriations Act (Pub. L 116-260) required APHIS to propose to lift the stay on the final rule establishing contingency plan requirements within 180 days of issuance of that Act.

On June 25, 2021, we published in the *Federal Register* (86 FR 33567-33570, Docket No. APHIS-2020-0101) a proposal<sup>3</sup> to lift the stay and make minor changes to the contingency plan regulations. These changes included updating the compliance dates by which regulated entities must create their contingency plans to 180 days after the effective date of this final rule; modifying the dates regarding when regulated entities must provide training to personnel to 60 days after the contingency plan being put in place; removing an extraneous reference to additional requirements for marine mammals to minimize confusion; removing the requirement that facilities as well as dealers, exhibitors, intermediate handlers, and carriers document their personnel's participation in requisite trainings; and adding a reference to a new optional form that entities may use to develop and document a contingency plan.

We solicited comments concerning our proposal for 60 days ending August 24, 2021. We received 140 submissions representing 35,654 comments by that date (one of the submissions had 35,000-plus form comments in support of the rule attached). They were from non-profit organizations; businesses; an association of research centers; national and state associations for biomedical research; associations of zoos, aquariums, and marine parks; veterinary associations; animal welfare organizations; and members of the public.

Of the 140 submissions, 138 supported the rule, and most exhorted us to finalize it without change to the rule or supporting documents. The comments that we received are discussed below by topic.

---

<sup>3</sup> To view the proposed rule, the comments we received, and supporting documents go to [www.regulations.gov](http://www.regulations.gov) and type APHIS-2020-0101 into the Search field.

## Contingency Plans

One commenter claimed that creating a contingency plan would be impossible for them because they had too many animals spread over too much acreage to shelter them in one location in the event of an emergency. The commenter noted that their animals used scattered shelters in extreme weather and that their geographical location was not at risk of flooding.

The regulations require entities to identify potential emergencies or disasters they are likely to experience and outline specific tasks to take (such as evacuation or shelter-in-place instructions) in the event that these situations occur.

The use of scattered shelters in extreme weather is an example of what could be an appropriate response to a potential emergency or disaster depending on an entity's circumstances. As such, the regulations authorize their use, if a regulated entity considers them appropriate based on the entity's unique circumstances. The regulations also do not require an entity to plan a response to flooding if flooding could not reasonably be anticipated.

Another commenter suggested that, instead of requiring entities to create contingency plans, USDA should provide yearly educational coaching on best practices for facility management and animal care.

While USDA inspectors will provide advice on facility management and animal care during inspections, such advice is not a sufficient replacement for this rule. The adverse events due to lack of planning detailed in the proposed rule and its supporting economic analysis outline the need for regulatory action. Accordingly, APHIS maintains that regulations are necessary to ensure the safety and well-being of animals under the care of regulated entities in compliance with the AWA.

Four commenters suggested APHIS provide additional resources for entities creating contingency plans, such as training materials, webinars, or links for further reading.

APHIS AC will conduct internal and external webinars regarding contingency planning and provide outreach materials on the APHIS website such as Frequently Asked Questions, aids, resources for further reading, and contact information in case entities have further questions.

Another commenter suggested that USDA develop sample templates, provide training for USDA inspectors who will help entities develop contingency plans, and obtain funding for this training.

As stated in the proposed rule, APHIS has provided an optional form that regulated entities may use as a template. This template was published alongside the proposed rule and will be available on the APHIS website. The APHIS website will also include various outreach materials to assist with contingency planning. AC's Center for Animal Welfare has developed a plan to implement the contingency planning regulations and has trained its personnel accordingly. This training is possible without additional funding apart from that appropriated by Congress for AC's ongoing operations.

Another commenter asked for the contingency requirements to be more prescriptive. Specifically, the commenter wanted APHIS to require entities to create contingency plans for the potential death of an owner and heat waves.

The regulations require a regulated entity to identify emergencies or disasters that could reasonably be anticipated and that would be detrimental to the well-being of their animals. We expect that, for most entities, it would be difficult to reasonably anticipate death.

If an entity determines that they are located in an area prone to heat waves that could be reasonably anticipated to be harmful to their animals, they would need to address heat waves in their contingency plans. However, an entity located in an extremely temperate climate may assess climatic conditions and determine a heat wave to be unlikely. APHIS believes that regulated entities themselves are best suited to make such determinations, and therefore will not provide a one-size-fits-all list of emergencies or disasters that all entities must plan for.

Another commenter requested explicit acknowledgement that plans developed for compliance with The Guide for the Care and Use of Laboratory Animals (The Guide) comply with this rule's contingency plan regulations.

Contingency plans developed using The Guide are acceptable so long as they fulfill the requirements laid out in the regulations.

The commenter also requested assurance that APHIS will not view deviations from contingency plans in emergency situations as violations, but as on-the-ground efforts to tailor the plan to specific events and opportunities to improve the contingency plan.

APHIS agrees with the commenter that the actual response may vary from the written contingency plan in an emergency situation, and that these variations can serve as a basis for updating and improving a contingency plan. If an entity varies its response from its written contingency plan in order to better meet the needs of an unfolding emergency situation, this would not necessarily be viewed as a violation. In such situations, APHIS would determine whether or not a violation has occurred on a case-by-case basis, based on whether the deviation furthers the purpose of the regulation, which is to safeguard the health and welfare of animals in the event of possible emergencies or disasters.

One commenter suggested requiring regulated entities to submit their contingency plans to USDA for review.

We are making no changes in response to the commenter. Submitting a plan to APHIS is not the sole means to demonstrate that a plan has been developed and satisfies the requirements of the regulations, and would impose a significant resource constraint on AC to receive and compile the plans and ensure their confidentiality. Rather, AC will ensure compliance with this rule through reviewing the entity's plan during announced and unannounced inspections. We believe that this method of enforcing the requirements provides sufficient assurance that the contingency planning requirements are being met while minimizing regulatory burden on entities and more efficiently allocating agency resources.

One commenter urged APHIS to take further action to ensure that an entity's contingency plans are kept confidential.

APHIS will not maintain the plans. Therefore, this rule does not raise confidentiality concerns.

## Training

A commenter wrote that the regulatory text should overtly state that it is up to the regulated entity to determine who needs to be trained and how.

The entity is responsible for including all personnel encompassed by the plan in the training and is responsible for the content and delivery of the training. We do not believe it is necessary to add this statement into the regulatory text, as the regulations do not state or imply otherwise.

The commenter also asked that the regulatory text clarify that only substantive changes to a contingency plan would necessitate updated training.

We agree with the commenter that non-substantive changes, which could include revisions as minor as reordering of instructions or grammatical corrections, do not necessitate updated training, and have made this change in §§ 2.38(l)(3) and 2.134(c). Our intent was that only substantive changes, that is, changes that materially alter the plan, would require updated training.

The commenter also asked that the 60- or 30-day training deadlines that we proposed be extended to 90 days for both initial and subsequent training of personnel.

We are making no changes in response to this comment. Training required by the regulations entails familiarizing personnel with their roles and responsibilities as outlined in the contingency plan. APHIS believes the deadlines in the proposed rule (60 days for initial training and 30 days for new employees and updates to the contingency plan) are sufficient time to

provide this basic training, and the commenter did not provide information suggesting this basic training could not be accomplished within that time period.

As noted above, we proposed to remove a requirement from the stayed final rule that facilities as well as dealers, exhibitors, intermediate handlers, and carriers document their personnel's participation in requisite trainings. Seven commenters disagreed with our proposed removal and asked for it to be reinstated.

APHIS does not believe that requiring entities to keep training records would significantly increase compliance with the training requirements, but it would increase burden on regulated entities.

Rather than require documentation, we will evaluate compliance with the training requirement through discussions with the licensee or registrant during announced and unannounced inspections. APHIS AC successfully enforces other training requirements in this manner, and is confident that this model will work for the regulations promulgated in this rule as well. Therefore, we are making no change in response to the commenters.

#### Economic Analysis

Two commenters stated that our estimates for the time it will take entities to create contingency plans and train personnel are too low.

Our estimates are averages based on the varying sizes of the entities and the optional fillable template the agency is providing. Some entities may require less time, and some will require more. Additionally, based on the comments received, it appears that most entities will not be formulating their plans de novo. Several commenters who were regulated entities themselves opined that it would be difficult for a regulated entity to remain operational without at least some contingency planning, and a few commenters stated that the regulated entities they represented already have contingency plans in place that meet the requirements of the rule. Indeed, one of the commenters who stated that our estimates were too low also stated that the



entities that it represents already have plans in place and should not incur new costs as a result of the rule.

Based on the comments received, we believe that the 1-to-2-hours for plan creation and 1 hour for training estimates, relative to the current plans maintained and training conducted by the entity, are reasonable.

One commenter stated that costs are unlikely to drop to zero after the first year.

We are not assuming that there will be no reoccurring annual costs after the first year of the implementation of the rule. We believe that the costs after the first year of developing and implementing contingency plans will decrease for existing entities as they would have already incurred the initial development and implementation costs.

The commenter also stated that, while they agree that capital costs will vary between entities, these costs will not be minimal.

The proposed rule did not prescribe any capital investments that entities must make. The entities vary by size and type and will have different requirements in terms of equipment. While some entities may incur costs to purchase equipment, others may already have equipment as a part of their business operations. We also note that the same commenter stated that the entities it represents had already assumed those costs apart from this rule as a cost of doing business.

#### Environmental Analysis

One commenter questioned why an environmental analysis was prepared, since they expected contingency plans to have only a positive impact on the environment.

APHIS conducted an environmental assessment based on the Council on Environmental Quality's (CEQ's) newly revised implementing procedures. The National Environmental Policy Act (NEPA) reviews all potential impacts, not just those with negative implications (40 CFR 1508.1(g)(1)).

#### Other Comments

A commenter asked that contingency plan regulations for marine mammals in

9 CFR 3.101(b) be eliminated.

This is outside of this rule's scope.

A commenter stated that there was a lack of a clear definition for the term "breeding female" as used in AWA regulations.

This is also outside of this rule's scope.

#### Miscellaneous

Finally, in reviewing the proposed rule with an eye toward implementation, we noticed that the explanations of training deadlines in §§ 2.38(l)(3) and 2.134(c) were ambiguous and did not clearly reflect APHIS' intent in drafting the proposed rule. We intended to state that if an employee was hired before or up to 30 days after a facility has its plan in place, that employee would have to be trained within 60 days of the plan being in place, whereas, if an employee was hired after that date, the facility would have 30 days to train the employee. However, the proposed rule could be read to suggest that employees hired at least 30 days before the plan is put in place must be trained by the time the plan is put in place, which would require training in the provisions of the plan before the plan itself was finalized. Requiring training in a plan that is not yet finalized and in place could be logistically problematic for regulated entities and, again, was not APHIS' intent. We have revised the paragraphs accordingly to make our intent clearer.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

#### Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. Copies of the full analysis are available on the Regulations.gov website (see footnote 3

in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

We are amending the AWA regulations to implement contingency plans for the handling of animals during emergencies. In December 2012, the USDA's APHIS published a final rule requiring all dealers, exhibitors, intermediate handlers, carriers, research facilities, and other entities regulated under the AWA to take steps to be better prepared for potential emergencies and disasters (situations which could reasonably be anticipated and expected to be detrimental to the good health and well-being of the animals in the regulated entity's possession). In July 2013, USDA issued a stay of the Contingency Plan Regulation in order to undertake a review of its requirements. In June of 2021, we published a proposed rule to lift the stay on the December 2012 rulemaking along with other minor administrative changes. This final rule will codify the provisions of the proposed rule and lift the stay on the 2012 final rule.

While it is difficult to quantify the benefits of contingency planning, they are numerous. First, contingency planning can prevent loss of animal life and any resulting undisposed carcasses that pose a threat to public health. Second, loss of valuable research resources and income can be mitigated with contingency planning. Third, having a contingency plan can reduce the time of recovery from disasters and thus provide cost savings to the affected businesses and organizations and allow for business continuity. Finally, required contingency planning will reassure the general public that facilities have measures in place to ensure the welfare of the animals in times of catastrophic and common emergencies.

APHIS' AC program will be providing a fillable form that can be used to develop and document the contingency plan; however, entities that have contingency plans in place may use those. For example, we believe that U.S. Public Health Service-funded research facilities and AZA zoos and aquariums have already developed contingency plans; they will not need to adopt the template. The template is intended to aid entities currently without a written contingency plan, and we estimate it will take on average 1-2 hours per entity to complete the plan, which

includes the time to collect and document the required information. We anticipate that the use of this form will improve compliance and expedite the time for annual review by regulated entities of the plan. APHIS also estimates it will take, on average, 1 hour to train employees on the operations of the plan, which consists of familiarizing employees with their roles and responsibilities as outlined in the plan.

We estimated lower and upper range estimates of costs for licensees and registrants to develop contingency plans in the first year. As noted above, we assume an average of 1 to 2 hours is required to prepare and implement a contingency plan using the form and 1 hour for employee training in the first year. We multiplied this time by the average industry-specific wage rate of the entities. Our estimate of the total one-time cost to develop the contingency plans across all affected entity categories ranges from about \$185,000 to about \$370,000 and \$185,000 for employee training, as well as possible capital costs, which will differ from entity to entity and which we accordingly are not able to estimate in aggregate. These estimates may be high, given our inclusion of entities that may currently have comparable contingency plans and already provide employee training, but for which we lack verifying information.

The 1 to 2 hours that we assume would be required to develop a contingency plan includes the time needed to identify resources for the plan's preparation and documentation. The 1-hour training estimate for all current and new employees considers the time it would take an employee to become familiar with their roles and responsibilities as outlined in the plan. The costs included in this analysis reflect training for the first year only. Contingency planning also requires record keeping, ensuring that the contingency plans are kept current, and employee training. The type of training and type of contingency plan required may differ depending on the type of organization or business, as well as its location and the location's climate history.

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

#### Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. The Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

#### National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this final rule. The environmental assessment provides a basis for the conclusion that the creation of contingency plans will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) NEPA, as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the CEQ for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment and finding of no significant impact may be viewed on the Regulations.gov website.<sup>4</sup> Copies of the environmental assessment and finding of no significant impact are also available for public inspection at USDA, room 1620, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead

---

<sup>4</sup> Go to [www.regulations.gov](http://www.regulations.gov). Enter APHIS-2020-0101 in the Search field. The environmental assessment and finding of no significant impact will appear in the list of documents.

on (202) 799-7039 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under FOR FURTHER INFORMATION CONTACT.

#### Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

#### Paperwork Reduction Act

In accordance with Section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this final rule have been submitted to the Office of Management and Budget (OMB) for approval under control number 0579-0479. When OMB notifies us of its decision, if approval is denied, we will publish a document in the *Federal Register* providing notice of what action we plan to take.

#### E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851-2483.

#### List of Subjects in 9 CFR Part 2

Animal welfare, Pets, Reporting and recordkeeping requirements, Research.

Accordingly, we are amending 9 CFR part 2 as follows:

#### PART 2—REGULATIONS

1. The authority citation for part 2 continues to read as follows:

Authority: 7 U.S.C. 2131-2159; 7 CFR 2.22, 2.80, and 371.7.

2. Amend § 2.38:

- a. By lifting the stay on paragraph (l) published at July 31, 2013 (78 FR 46255);
- b. In paragraph (l)(2):
  - i. In the first sentence by removing the date “July 29, 2013” and adding “July 5, 2022” in its place;
  - ii. In the fifth sentence by removing the words “and training records”; and
  - iii. By revising the last sentence; and
- c. By revising paragraph (l)(3); and
- d. By adding an OMB citation at the end of the section.

The revisions and addition read as follows:

§ 2.38 Miscellaneous.

\* \* \* \* \*

(l) \* \* \*

(2) \* \* \* The APHIS Contingency Plan form may be used to keep and maintain the information required by paragraph (l)(1) and (2) of this section..

(3) The facility must provide training for its personnel regarding their roles and responsibilities as outlined in the plan. For current registrants, training of facility personnel must be completed within 60 days of the research facility putting their plan in place; for research facilities registered after July 5, 2022, training of facility personnel must be completed within 60 days of the facility putting its contingency plan in place. This deadline applies to employees hired before and up to 30 days after the facility puts its contingency plan in place. For employees hired more than 30 days after the facility puts its contingency plan in place, training must be conducted within 30 days of their start date. Any substantive changes to the plan as a result of the annual review must be communicated to employees through training which must be conducted within 30 days of making the changes.

(Approved by the Office of Management and Budget under control number 0579-0479)

3. Amend § 2.134:

- a. By lifting the stay on the section published July 31, 2013 (78 FR 46255);
- b. In paragraph (b):
  - i. In the first sentence by removing the date “July 29, 2013” and adding “July 5, 2022” in its place;
  - ii. In the fifth sentence by removing the words “and training records”; and
  - iii. By revising the last sentence; and
- c. By revising paragraph (c); and
- d. By adding an OMB citation at the end of the section.

The revisions and addition read as follows:

§ 2.134 Contingency planning.

\* \* \* \* \*

(b) \* \* \* The APHIS Contingency Plan form may be used to keep and maintain the information required by § 2.38(l)(1) and (2).

(c) Dealers, exhibitors, intermediate handlers, and carriers must provide training for their personnel regarding their roles and responsibilities as outlined in the plan. For current licensees and registrants, training of dealer, exhibitor, intermediate handler, and carrier personnel must be completed within 60 days of the licensee and registrant putting their contingency plan in place; for new dealers, exhibitors, intermediate handlers, or carriers licensed or registered after July 5, 2022, training of personnel must be completed within 60 days of the dealer, exhibitor, intermediate handler, or carrier putting their contingency plan in place. This deadline applies to employees hired before and up to 30 days after the date the licensee or registrant puts its contingency plan in place. For employees hired more than 30 days after the date the licensee or registrant puts its contingency plan in place, training must be conducted within 30 days of their start date. Any substantive changes to the plan as a result of the annual review must be communicated to employees through training which must be conducted within 30 days of making the changes.



(Approved by the Office of Management and Budget under control number 0579-0479)

Done in Washington, DC, this 26th day of November 2021.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021-26174 Filed: 12/2/2021 8:45 am; Publication Date: 12/3/2021]